UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF VIRGINIA
CHARLOTTESVILLE DIVISION

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PBM PHARMACEUTICALS, INC. AND CONCORDIA PHARMACEUTICALS INC.

Plaintiffs,

Civil Action No. 3:14-cv-00016-GEC

v.

METHOD PHARMACEUTICALS, LLC AND WINDER LABORATORIES, LLC

Defendants.

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SECOND AMENDED COMPLAINT

Plaintiffs PBM Pharmaceuticals, Inc. and Concordia Pharmaceuticals Inc. ("Plaintiffs"), by and through their undersigned counsel, for their Complaint against Defendants Method Pharmaceuticals, LLC and Winder Laboratories, LLC ("Defendants"), hereby allege and state the following:

INTRODUCTION

1. For nearly 80 years, Plaintiffs' Donnatal® brand of pharmaceutical products has helped improve the lives of individuals suffering from irritable bowel syndrome (IBS), a condition characterized by abdominal pain, bloating, and irregular diarrhea or constipation.

2. Plaintiffs distribute and market Donnatal in two unique formulations: (1) immediate release Donnatal Tablets and (2) fast-acting Donnatal Elixir, available in either grape or mint flavor.

3. The active formulation in Donnatal comprises a combination of phenobarbital and belladonna alkaloids ("PBA").

4. Defendants saw an opportunity to exploit the success of Donnatal by creating a knock-off PBA product that it is calling "Me-PB-Hyos." Defendants falsely represent that Me-PB-Hyos is available in tablet and elixir form, and functions as a generic substitute for Donnatal.

5. Plaintiffs bring this action for injunctive relief to stop Defendants from falsely representing Me-PB-Hyos as a legal, generic equivalent to Donnatal. Plaintiffs also seek damages resulting from Defendants' unlawful conduct, including damages for harm to Plaintiffs' reputation and goodwill.

THE PARTIES

6. Plaintiff PBM Pharmaceuticals, Inc. ("Plaintiff PBM"), conducting business under the name Revive Pharmaceuticals, is a Delaware corporation having its principal place of business in Charlottesville, Virginia. Plaintiff PBM is a specialty pharmaceutical company that focuses on revitalizing popular pharmaceutical products placed into lifecycle management by larger pharmaceutical companies. In addition, Plaintiff PBM is a 16.17% shareholder of Concordia Healthcare Corp., which is the ultimate parent company of Plaintiff Concordia Pharmaceuticals Inc. ("Plaintiff Concordia"). Plaintiff PBM provides certain services to Concordia Healthcare Corp., including receipt, acceptance and processing of orders, billing of customers, collection of payments and performance of other ancillary services relating to the Donnatal product line.

7. Plaintiff Concordia is an international business company incorporated under the law of Barbados, having its principal place of business in Bridgetown, St. Michael, Barbados.

On May 15, 2014, Plaintiff Concordia completed the acquisition of the Donnatal product line from Plaintiff PBM.

8. Upon information and belief, Defendant Method Pharmaceuticals, LLC ("Defendant Method") is a Texas limited liability company with its principal office at 2000 East Lamar Boulevard, Suite 600, Arlington, Texas 76006. Method is the labeler for the Me-PB-Hyos products.

9. Upon information and belief, Defendant Winder Laboratories, LLC ("Defendant Winder") is a Georgia limited liability company with its principal office at 716 Patrick Industrial Lane, Winder, Georgia 30680, and the manufacturer of the Me-PB-Hyos products.

JURISDICTION

10. This Court has subject matter jurisdiction over the claims pursuant to 28 U.S.C. §§ 1331 and 1338. The Court also has supplemental jurisdiction over Plaintiffs' state and common law claims pursuant to 28 U.S.C. § 1367.

11. Venue is proper in this district pursuant to 28 U.S.C. § 1391. A substantial part of the events giving rise to the claims against Defendants occurred in this District.

12. This Court has personal jurisdiction over Defendants because the Defendants have listed their products for sale in online databases that are used by purchasers of PBA pharmaceuticals in this District, and, accordingly, Defendants have purposefully directed their business activities toward this District. In addition, the Defendants have caused harm to Plaintiffs in this District. Through such conduct, Defendants have purposefully availed themselves of the privileges of conducting business in this District, and, when engaging in such

conduct, it was reasonably foreseeable that Defendants would be subjected to this Court's jurisdiction.

BACKGROUND FACTS

13. According to the National Institute of Health, as many of 30% of Americans suffer from IBS at some point in their lives. IBS can severely compromise an individual's quality of life, and is second only to the common cold as a cause of absenteeism from work.

14. Donnatal is a proprietary combination medicine used as adjunctive therapy in the treatment of IBS, as well as acute enterocolitis. Because Donnatal requires use under the supervision of a healthcare provider, it is available by prescription only.

15. The Donnatal products were first introduced in the market by A.H. Robins Company ("Robins") in 1936. Plaintiff PBM is the successor-in-interest to Robins, and owned and marketed the Donnatal products from 2001 until the acquisition of Donnatal by Plaintiff Concordia on May 15, 2014. Plaintiff PBM retains an interest in the Donnatal products as a 16.17% shareholder of Concordia Healthcare Corp., ultimate parent of Plaintiff Concordia, and as the provider of certain services related to the Donnatal product line.

16. In 1962, when Congress amended the Federal Food, Drug and Cosmetic Act ("FD&C Act"), the Food and Drug Administration (FDA) was required to conduct a retrospective evaluation of drugs that had previously been approved under the FD&C Act between its enactment in 1938 and 1962. Donnatal was one of more than 3,400 drugs affected by this amendment. 21 U.SC. § 301 *et seq.*

17. In the 1970s, the FDA began a process of evaluating the safety and efficacy of PBA drug products under the Drug Efficacy Study Implementation ("DESI") review program. On June 20, 1978, the FDA required any drugs that were involved in the review process to obtain an approved New Drug Application ("NDA") or Abbreviated New Drug Application ("ANDA") to remain on the market. 43 Fed. Reg. 26,490 (June 20, 1978).

18. On December 30, 1980 Plaintiffs' predecessor, Robins, obtained conditional approval ANDAs for its Donnatal Tablets (ANDA 88-676) and Donnatal Elixir (ANDA 86-661). Conditionally approved ANDAs have the same status as safety-only NDAs that had been approved prior to the 1962 Amendments. Drug products manufactured under such a conditionally approved ANDA can be legally marketed until the FDA resolves questions about their effectiveness under the FD&C Act.

19. On May 6, 1983, the FDA published in the Federal Register a notice of an opportunity for a hearing ("NOOH") regarding the regulatory status of PBA drug products, including Donnatal. Under the FD&C Act, the FDA requires the holders of approved NDAs or those alleging such approvals to submit clinical evidence within 60 days of the NOOH showing that genuine and material issues of fact exist about the effectiveness of the drug that require an administrative hearing for resolution.

20. In response to the NOOH, Robins submitted substantial clinical evidence that raised genuine and material issues supporting the effectiveness of Donnatal.

21. Under the NOOH process, only those companies that actively participated in this hearing process were permitted to legally market their PBA drug products. Plaintiffs' Donnatal products have been under this NOOH since 1983, and thus have been allowed to continue to

remain on the market pending final resolution of the hearing process. The hearing process for PBA products has not yet been completed.

22. In July 2011, in response to a notice from the FDA seeking clarification of the ownership of Donnatal, Plaintiff PBM submitted information demonstrating that Plaintiff PBM was the successor-in-interest to Robbins, and additional substantial clinical evidence and data supporting the effectiveness of the Donnatal products. This submission further clarified Plaintiff PBM's legal basis for marketing its products.

23. Upon information and belief, Plaintiffs are the only companies that continue to participate in the FDA DESI review process for PBA products.

24. In September 2011, the FDA established a Compliance Policy Guide confirming that any drug product coming to market for the first time after September 19, 2011 alleging any legal status under the DESI review was illegal and subject to immediate legal action by the FDA.

25. Accordingly, upon information and belief, Plaintiffs are the only companies that are legally permitted to market PBA products.

DEFENDANTS' UNLAWFUL CONDUCT

26. On or around April 2, 2014, listings for Defendants' "Me-PB-Hyos Oral Elixir" and "Me-PB-Hyos Oral Tablets" appeared in medical database Medi-Span. Copies of the listings are attached as Exhibit A.

27. Medi-Span is a prescription drug information and interactions database used nationwide by health care professionals, payers and pharmaceutical manufacturers to evaluate

medications that are currently or will soon be on the market. Medi-Span is also used to determine whether generic substitutes are available for brand name products.

28. Pharmaceuticals that are pharmaceutically equivalent are assigned the same Generic Product Identifier ("GPI") and are "linked" to one another. This linkage information is used by pharmacists, pharmaceutical buyers, and insurance companies to determine whether there are any generic alternatives to a particular brand product.

29. Pharmaceutical equivalence means that the products contain the same active ingredients, in the same amounts, and in the same dosage forms.

30. The Medi-Span listings for "Me-PB-Hyos" show that Defendants' pharmaceuticals have been "linked" to one another.

31. Accordingly, Defendants claim that their Me-PB-Hyos pharmaceuticals contain ingredients identical to those in Plaintiffs' Donnatal and that the pharmaceuticals are pharmaceutically equivalent.

32. In addition, by listing their Me-PB-Hyos products on Medi-Span after September 19, 2011, when the FDA unequivocally made approval for new products entering the market mandatory, Defendants are misleading consumers that their products have been approved by the FDA.

33. In order to be listed in Medi-Span, an applicant must normally submit an FDA Approval Letter and the corresponding approval number. *See* Exhibit B.

34. The FDA would not have provided an Approval Letter or approval number to Defendants because the Defendants do not have an approved NDA or ANDA for their drug products, nor were they participants in the FDA's DESI review process for PBA products.

35. In addition, on or about June 3, 2014, Defendant Method submitted their Me-PB-Hyos products for listing in medical database First DataBank.

36. When First DataBank asked Defendant Method about the approval status of Donnatal, Defendants falsely claimed to First DataBank that Plaintiffs' Donnatal was not approved by the FDA.

37. Further, by submitting their Me-PB-Hyos products for listing with First DataBank after September 19, 2011, when the FDA unequivocally made approval for new products entering the market mandatory, Defendants are misleading consumers that their products have been approved by the FDA.

38. Upon information and belief, Defendants intend to bring their Me-PB-Hyos products to market in February 2015, and are actively marketing and promoting the Me-PB-Hyos products.

39. Defendants' listings of their Me-PB-Hyos products have been made available to Plaintiffs' customers in this District and have adversely impacted Plaintiffs' sales of their Donnatal products in this District.

40. Upon information and belief, pharmaceutical databases Medi-Span and First DataBank recently removed the Me-PB-Hyos listings from their databases because Defendants'

products are currently unavailable, and will allow Defendants to re-submit Me-PB-Hyos for listing when the products come to market.

41. The false and misleading information in the listings has been made available to customers, and will be made available again in the near future, upon or prior to Defendants' first sale of Me-PB-Hyos products.

42. Upon information and belief, wholesalers and pharmacies have reduced inventories of Donnatal in anticipation of Defendants' launch of Me-PB-Hyos.

43. Accordingly, pharmacists attempting to order Donnatal are unable to fill prescriptions because of the presence of Me-PB-Hyos on medical databases as a generic alternative. Pharmacists options' include 1) refusing to fill the patients' prescription, 2) ordering Donnatal at a loss, since the pharmacy will only be reimbursed by insurance companies at the "generic" product rate, despite the fact that no generic is available, 3) participating in a burdensome "override" process with the insurance companies, or 4) calling the patient's doctor about ordering a different drug.

44. When pharmacists contact a patient's doctor regarding ordering a drug other than Donnatal, the doctor is unlikely to prescribe Donnatal in the future, knowing that patients will not be able to easily purchase the PBA pharmaceuticals. These patients (and sales) are likely to be lost to Plaintiffs forever, even though Donnatal may be the preferred prescription for the patient.

45. When Me-PB-Hyos comes onto the market, Plaintiffs will suffer an immediate and substantial loss in market share.

46. In addition, patients will be exposed to a drug that has not been safety-approved by the FDA. Besides the threat to public health, adverse effects may be attributed to Donnatal because patients are often unaware of the substitution, thus resulting in the erosion of Plaintiffs' goodwill.

47. Defendants' promotion, marketing and listing of PBA pharmaceuticals that falsely claim to be pharmaceutically equivalent to Plaintiffs' Donnatal products is prohibited by law, has caused irreparable injury to Plaintiffs, and will continue to both damage Plaintiffs and to deceive and potentially harm the public unless enjoined by this Court.

48. When the false Me-PB-Hyos listings came to Plaintiff PBM's attention, Plaintiff PBM promptly contacted Defendant Method regarding its unlawful conduct. In response, Defendant Method claimed that PBA pharmaceuticals are available to be marketed by anyone, and that Plaintiff PBM did not possess the exclusive rights to market these products.

49. Plaintiffs have been and will be harmed by Defendants' false and misleading representations. Defendants' efforts have and will continue to mislead consumers into believing that Me-PB-Hyos is pharmaceutically equivalent to and may be used interchangeably with Donnatal. Defendants' efforts have harmed and will continue to harm Plaintiffs' unique brand, through which purchasers of PBA pharmaceuticals have come to recognize Plaintiffs as the only FDA-approved entities currently allowed to market PBA pharmaceuticals.

COUNT I

FALSE ADVERTISING IN VIOLATION OF LANHAM ACT SECTION 43(a) (15 U.S.C. § 1125(a))

50. Plaintiffs repeat and re-allege each and every allegation contained in the preceding paragraphs of this Complaint, and incorporate them herein by reference.

51. Defendants' representations that Me-PB-Hyos pharmaceuticals are FDA-approved, PBA products substitutable for Donnatal pharmaceuticals based on pharmaceutical equivalency are false or misleading representations of fact.

52. Defendants' statements have actually deceived or have the tendency to deceive a substantial segment of their audience.

53. Defendants' claims that their goods are a generic alternative for Plaintiffs' Donnatal pharmaceuticals are material and likely to influence the purchasing decisions of health care professionals and patients who consume Plaintiffs' products.

54. Defendants' false or misleading representations were and are made in interstate commerce.

55. Defendants' representations are in direct violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), which provides in relevant part that "[a]ny person who, in connection with any goods or services...uses in commerce any…false or misleading representation of fact, which in commercial advertising or promotion, misrepresents the nature, characteristics, qualities or geographic origin of his or her or another person's goods, services, or commercial activities, shall be liable in a civil action by any person who believes that he or she is likely to be damaged by such act."

56. As a direct and proximate result of Defendants' conduct, Plaintiffs have suffered and are continuing to suffer irreparable injury, including irreparable injury and damages, which includes a loss of sales and profits, which Plaintiffs would have made but for the false and deceptive representations by Defendants.

57. Pursuant to 15 U.S.C. § 1116, Plaintiffs are entitled to preliminary and permanent injunctive relief to Defendants' continuing acts.

COUNT II

UNFAIR COMPETITION IN VIOLATION OF LANHAM ACT SECTION 43(a) (15 U.S.C. § 1125(a))

58. Plaintiffs repeat and re-allege each and every allegation contained in the preceding paragraphs of this Complaint, and incorporate them herein by reference.

59. Plaintiffs' Donnatal has become uniquely associated with and identifies Plaintiffs as the only FDA-approved providers of PBA pharmaceuticals.

60. Defendants' representations that Me-PB-Hyos is pharmaceutically equivalent to Donnatal, and is an FDA-approved PBA pharmaceutical, have deceived, misled and confused consumers and enabled Defendants to trade off of Plaintiffs' reputation and goodwill.

61. Defendants' acts constitute unfair competition in violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a).

62. By reason of Defendants' conduct, Plaintiffs have suffered and will continue to suffer damage to their business, reputation and goodwill.

63. Pursuant to 15 U.S.C. § 1117, Plaintiffs are entitled to damages for Defendants' Lanham Act violations.

64. Defendants' acts are willful, wanton and calculated to deceive, and are undertaken in bad faith, making this an exceptional case entitling Plaintiffs to recover additional damages and their reasonable attorney fees pursuant to 15 U.S.C. § 1117.

65. Defendants' conduct has caused, and unless enjoined by this Court, will continue to cause immediate and irreparable harm to Plaintiffs for which there is no adequate remedy at law. Accordingly, Plaintiffs are additionally entitled to injunctive relief.

COUNT III

VIRGINIA CONSUMER PROTECTION ACT
(Va. Code § 59.1-200)

66. Plaintiffs repeat and re-allege each and every allegation contained in the proceeding paragraphs of this Complaint, and incorporate them herein by reference.

67. Defendants, by virtue of their Me-PB-Hyos database listings, misrepresent that their pharmaceuticals are pharmaceutically equivalent to and can be used a generic substitute for Donnatal in violation of Va. Code § 59.1-200(5).

68. Defendants, by virtue of their Me-PB-Hyos database listings, misrepresent that their pharmaceuticals are approved by the FDA and are legally marketed in violation of Va. Code § 59.1-200(2).

69. As a proximate result of Defendants' misrepresentations, Defendants' conduct has caused, and unless enjoined by this Court, will continue to cause immediate and irreparable

harm, for which Plaintiffs are entitled injunctive relief and damages in an amount to be proven at trial.

COUNT IV

COMMON LAW CIVIL CONSPIRACY

70. Plaintiffs repeat and re-allege each and every allegation contained in the preceding paragraphs of this Complaint, and incorporate them herein by reference.

71. Defendants entered into an agreement and/or understanding, and otherwise conspired with one another and others as yet unnamed, to tortuously interfere with Plaintiffs' lawful businesses and misrepresent to the public that they are legally permitted to sell PBA products.

72. As a result of Defendants' actions, Plaintiffs have suffered and are continuing to suffer irreparable injury, including irreparable injury and damages, which includes a loss of sales and profits which Plaintiffs would have made but for the acts committed in pursuance of the conspiracy.

COUNT V

VIRGINIA BUSINESS CONSPIRACY
(Va. Code § 18.2-500)

73. Plaintiffs repeat and re-allege each and every allegation contained in the preceding paragraphs of this Complaint, and incorporate them herein by reference.

74. Defendants have associated, agreed, mutually undertaken or acted in concert together for the purpose of willingly or maliciously harming Plaintiffs' legal businesses. Specifically, Defendants have conspired to falsely represent to the public that they are authorized

by the FDA to promote and sell PBA products for the express purpose of interfering with Plaintiffs' current and prospective business relationships.

75. As a result of Defendants' actions, Plaintiffs have suffered and are continuing to suffer irreparable injury, including irreparable injury and damages, which includes a loss of sales and profits which Plaintiffs would have made but for the acts committed in pursuance of the conspiracy.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray that the Court enter judgment in their favor and grant the following relief:

A. Compensatory damages, consisting of general and special damages, in an amount to be proven at trial, including, but not limited to, treble damages pursuant to Va. Code § 18.2-500;

B. An award of punitive damages;

C. A preliminary and permanent injunction permanently enjoining Defendants and all others acting in privity or in concert with them from listing, marketing or offering for sale "Me-PB-Hyos" or other unauthorized PBA pharmaceuticals;

D. Reasonable attorney fees and costs in prosecuting this action as provided by § 35(a) of the Lanham Act, 15 U.S.C. § 1117 and Virginia law, including, but not limited to, Va. Code § 18.2-500;

E. Disgorgement of Defendants' profits from their unlawful acts and an accounting of such profit; and

F. Award Plaintiffs such other relief as the interests of justice may require.

DATE: October 31, 2014

Respectfully submitted,

PBM PHARMACEUTICALS, INC. AND
CONCORDIA PHARMACEUTICALS INC.

BY: /s/ S. Lloyd Smith

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Exhibit A

Price Rx

Product Information

User: Rett Crowder

April 11, 2014

NDC/UPC/HRI	Product Name	Package Size	Package SubUnit	Package Qty	Package Description	Labeler Name	Labeler Code
58657-0420-16	DM-PB-Hyos Oral Elixir 16.2 MG/5ML	473 ML		1	Bottle	METHOD PHARMACEUTICALS	58657

Medi-Span Classification		
Drug Range	46-52	Gastrointestinal Agents
Drug Group	49	ULCER DRUGS
Drug Class	49-10	Antispasmodics
Drug Subclass	49-10-99	Anticholinergic Combinations
Drug Base Name	49-10-99-02	Anticholinergic Combination - Two Ingredient
Drug Name	49-10-99-02-25	Belladonna Alkaloids-Phenobarbital
Drug Name And Dosage Form	49-10-99-02-25-10	Belladonna Alkaloids-Phenobarbital Elixir
GPI Name	49-10-99-02-25-10-10	Belladonna Alkaloids-Phenobarbital Elixir 16.2 MG/5ML
GPPC	02674-S49	Belladonna Alkaloids-Phenobarbital Elixir 16.2 MG/5ML, 473 ML, Bottle

Other Classifications		
UHFS	12060800	Antimuscarinics/Antispasmodics
NSC	29120	GI ANTISPASMODIC, BELLADONNA

NDC/UPC/HRI	Product Name	Package Size	[illegible]	Package Qty	Package Description	Labeler Name	Labeler Code
58657-0420-16	Me-PB-Hyos Oral Elixir 16.2 MG/5ML	473 ML			1 Bottle	METHOD PHARMACEUTICALS	58657

Product Details

NDC/UPC/HRI Type	1-NDC	UD/UU Code	S-Standard Packaging
Secondary Id	-	Inner Pack	No
NDC/UPC/HRI Eff Date	04/01/2014	Repack Code	No
nactive Date	-	Clinic Pack	No
New NDC/UPC/HRI		Maint Drug Code	No
Route	OR-Oral	Limited Distribution Code	00-NOT APPLICABLE
Rx/OTC	R-PRESCRIPTION	Dollar Rank Code	0-Not Ranked
TEE Code	NR-Not Rated	Rx Rank Code	0-Not Ranked
DEA Code	4-Limited abuse potential	Labeler Type Code	B-Promoted as "Brand"
DESI Code	5-Less than effective for all indications	Price Spread Code	1-Pricing Spread is ≤21%
Third Party Code	Not Applicable		

rand Probability Calculation

Multi-Source Code	Y-Multi-source product
Brand Name Code	B-Branded Generic Name
Drug Appl. Type (FDA)	Not Available
Drug Appl. Type (Mfr)	Not Available
Reference Listed Drug	Not Available
CMS Drug Cat Code	-
Brand Probability	23.63% (effective 4/2/2014)

Drug Application Information

Appl#	Type	Mktg Status		Mktg Date	Marketing Category

Current Prices

Source	PI	Package Price	Unit Price	Effective Date
AAWP		$0.00	$0.00000	07/12/2012
AWAC		$317.89	$0.67207	04/01/2014
AWP	S	$397.36	$0.84008	04/01/2014
DMS FUL		-	-	-
DP		-	-	-
GEAF		-	-	-
GEWAC		-	-	-
MADAC Chain Pharmacy		-	-	-
MADAC Independent Pharmacy		-	-	-
MAC		$317.89	$0.67207	04/01/2014

NDC/UPC/HRI History

Package NDC/UPC/HRI	Effective Date	Inactive Date

Dosages

Type	Amount
Min	10 ML
Usual	20 ML
Max	40 ML

Durations

Type	Amount
Min	1 day
Usual	30 days
Max	999 days

NDC/UPC/HRI	Product Name	Package Size	Package UM	Package Qty	Package Description	Labeler Name	Labeler Code
58657-0425-16	Me-PB-Hyos Oral Elixir 16.2 MG/5ML	473	ML	1	Bottle	METHOD PHARMACEUTICALS	58657

AWP		DP		WAC		CMS FUL		NADAC Independent Pharmacy		NADAC Chain Pharmacy	
Package Price	Effective	Package Price	Effective	Package Price	Effective	Package Price	Effective	Unit Price	Effective	Unit Price	Effective
$397.36	04/01/2014			$317.89	04/01/2014						

AAWP		GEAP		AWAC		GEWAC		ASP			
Package Price	Effective	Package Price	Effective	Package Price	Effective	Package Price	Effective	Quarter	Revision	HCPCS	Limit
$0.00	07/12/2012			$317.89	04/01/2014						

NDC/UPC/HRI	Product Name	Package Size	Package SMK	Package Description	Label Name	Label Code
58657-0420-16	Me-PB-Hyos Oral Elixir 16.2 MG/5ML	473 ML	1 BOTTLE		METHOD PHARMACEUTICALS	58657

GPI Cross Reference - Belladonna Alkaloids-Phenobarbital Elixir 16.2 MG/5ML (49-10-99-02-25-10-10) - Package Size 473

NDC/UPC/HRI	Product Name	AWP	DP	WAC	CMS FUL	MP	GEAF	AWAC	GEWAC	Labeler	OBRA	MS	NEEP	OTC
13925-0158-16	SE-Donna PB Hyos Oral Elixir 16.2 MG/5ML	$79.10		$63.88		$0.00		$317.89		SETON PHARMACEUTICALS	Y	NR		R
21695-0594-16	RE-PB Hyos Oral Elixir 16.2 MG/5ML	$149.10								PHYSICIAN PARTNER	Y	NR		R
21695-0970-16	Quadrapex Oral Elixir 16.2 MG/5ML	$159.74								PHYSICIAN PARTNER	Y	NR		R
42192-0520-16	Quadrapex Oral Elixir 16.2 MG/5ML	$79.87				$0.00		$317.89		ACELLA PHARMACEUTICALS	Y	NR		R
42291-0244-16	Donnatal Oral Elixir 16.2 MG/5ML	$498.93		$399.14		$0.00		$317.89		AVKARE	O	NR		R
49768-0395-16	PB-Hyos Oral Elixir 16.2 MG/5ML	$74.55	$53.13	$53.13		$0.00		$317.89		KYLEMORE PHARMACEUTICALS	Y	NR		R
58657-0420-16	Me-PB-Hyos Oral Elixir 16.2 MG/5ML	$397.36		$317.89		$0.00		$317.89		METHOD PHARMACEUTICALS	Y	NR		R
59032-0395-16	RE-PB Hyos Oral Elixir 16.2 MG/5ML	$74.55	$53.13	$53.13		$74.55		$53.13		KYLEMORE PHARMACEUTICALS	Y	NR		R

Ingredients (Set ID: 113561)

Ingredient Name	Strength	Unit	Active	Generic Code
ATROPINE SULFATE	0.0194	MG/5ML	Y	C000055481
HYOSCYAMINE SULFATE	0.1037	MG/5ML	Y	C000520611
PHENOBARBITAL	16.2000	MG/5ML	Y	C000050095
SCOPOLAMINE HYDROBROMIDE	0.0065	MG/5ML	Y	C000114498
ALCOHOL, USP	23.8000	%	N	C000064175
D&C BLUE #2 (INDIGOTINE)	0.0000		N	C000860220
D&C RED #40	0.0000		N	C025956176
SACCHARIN SODIUM	0.0000		N	C000126449

Price Rx

Product Information

April 11, 2014

lser: Rett Crowder

NDC/UPC/HRI	Product Name	Package Size	Package Size UM	Package Qty	Package Description	Labeler Name	Labeler Code
58657-0421-01	Me-PB-Hyos Oral Tablet 16.2 MG	100	EA	1	Bottle	METHOD PHARMACEUTICALS	58657

Medi-Span Classification

Drug Range	46-52	Gastrointestinal Agents
Drug Group	49	ULCER DRUGS
Drug Class	49-10	Antispasmodics
Drug Subclass	49-10-99	Anticholinergic Combinations
Drug Base Name	49-10-99-02	Anticholinergic Combination - Two Ingredient
Drug Name	49-10-99-02-25	Belladonna Alkaloids-Phenobarbital
Drug Name And Dosage Form	49-10-99-02-25-03	Belladonna Alkaloids-Phenobarbital Tablet
GPI Name	49-10-99-02-25-03-12	Belladonna Alkaloids-Phenobarbital Tab 16.2 MG
GPPC	28975-003	Belladonna Alkaloids-Phenobarbital Tab 16.2 MG, 100 Each, Bottle

Other Classifications

AHFS	12080800	Antimuscarinics/Antispasmodics
USC	23120	GI ANTISPASMODIC, BELLADONNA

NDC/UPC/HRI	Product Name	Pkg.	Package Size	Dosage Submitted	Package Description	Labeler Name	Labeler Code
58657-0421-01	Me-PR-Five-Oral Tablet 15-2 MG		100-EA		Route	METHOD PHARMACEUTICALS	58657

Product Details

NDC/UPC/HRI Type	1-NDC	UD/UU Code	S-Standard Packaging
Secondary Id		Inner Pack	No
NDC/UPC/HRI Eff Date	04/01/2014	Repack Code	No
Inactive Date		Clinic Pack	No
New NDC/UPC/HRI	-	Maint Drug Code	No
Route	OR-Oral	Limited Distribution Code	00-NOT APPLICABLE
Rx/OTC	R-PRESCRIPTION	Dollar Rank Code	0-Not Ranked
TEE Code	NR-Not Rated	Rx Rank Code	0-Not Ranked
DEA Code	4-Limited abuse potential	Labeler Type Code	B-Promoted as "Brand"
DESI Code	5-Less than effective for all indications	Price Spread Code	1-Pricing Spread is < 21%
Third Party Code	Not Applicable		

Brand Probability Calculation

Multi-Source Code	Y-Multi-source product
Brand Name Code	B-Branded Generic Name
Drug Appl. Type (FDA)	Not Available
Drug Appl. Type (Mfr)	Not Available
Reference Listed Drug	Not Available
CMS Drug Cat Code	
Brand Probability	23.03% (effective 4/2/2014)

Drug Application Information

Appl.	Mktg Start	Mktg End	Marketing Category

NDC/UPC/HRI	Product Name	Type	Package Size	Package SUM	Package Qty	Package Description	Labeler Name	Labeler Code
5657-042-01	Methotrexate Oral Tablet 15.2 MG		100 EACH		1 Bottle		METHOD PHARMACEUTICALS	55657

Current Prices

Type	Unit	Package Price	Unit Price	Effective Date
AWP		$0.00	$0.00000	01/31/2008
WAC		$335.68	$3.35680	04/01/2014
AWP	S	$419.80	$4.19800	04/01/2014
CMS FUL		-	-	-
DP		-	-	-
GEAP		-	-	-
GEWAC		-	-	-
NADAC Chain Pharmacy		-	-	-
NADAC Independent Pharmacy		-	-	-
WAC		$335.68	$3.35680	04/01/2014

NDC/UPC/HRI History

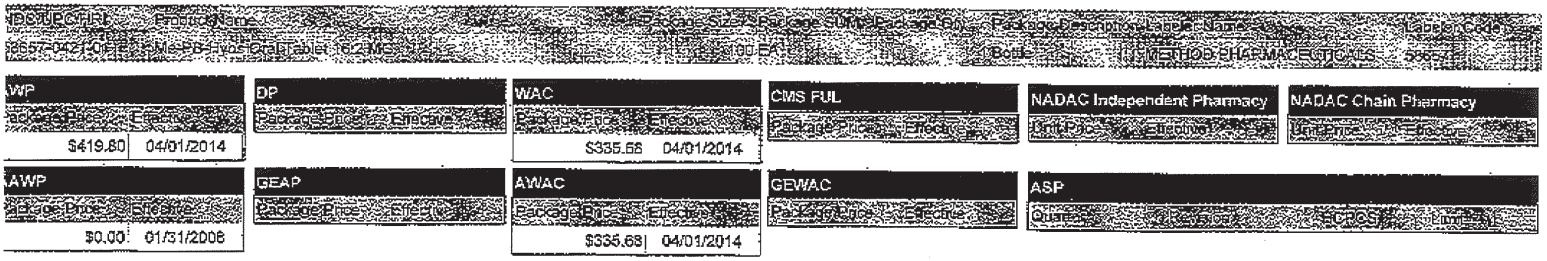
Previous NDC/UPC/HRI	Effective Date	Inactive Date

Dosages

Type	Amount
Min	3 EA
Usual	4 EA
Max	8 EA

Durations

Type	Amount
Min	1 day
Usual	30 days
Max	999 days



NDC/UPC/HRI	Product Name	Package Size	Package SDM	Package Qty	Package Description	Labeler Name	Labeler Code
52657-0421-01	Me-PB-Hyos Oral Tablet 16.2 MG	100	EA	100	Bottle	METHOD PHARMACEUTICALS	52657

GPI Cross Reference - Belladonna Alkaloids-Phenobarbital Tab 16.2 MG (49-10-99-02-25-03-12) - Package Size 100

NDC/UPC/HRI	Product Name	AWP	DP	WAC	CMS FUL AMT	GER PMA WAC	GER	Labeler	MSTE	
42291-0245-01	Donnatal Oral Tablet 16.2 MG	$513.50		$410.80	$0.00	$335.68		AVKARE	O	NR R
51655-0295-21	Donnatal Oral Tablet 16.2 MG	$2.15						PHARMACEUTICAL CORP OF AMERICA	O	NR R
54868-0031-00	Belladonna Alk-Phenobarbital Oral Tablet 16.2 MG	$27.58						PHYSICIANS TOTAL CARE	Y	NR R
54868-1237-01	Donnatal Oral Tablet 16.2 MG	$55.12						PHYSICIANS TOTAL CARE	O	NR R
55289-0035-01	Belladonna Alk-Phenobarbital Oral Tablet 16.2 MG	$15.94						PDRX PHARMACEUTICAL	Y	NR R
58016-0709-00	Belladonna Alk-Phenobarbital Oral Tablet 16.2 MG	$24.89						SOUTHWOOD PHARMACEUTICALS	Y	NR R
52657-0421-01	Me-PB-Hyos Oral Tablet 16.2 MG	$419.50		$335.68	$0.00	$335.68		METHOD PHARMACEUTICALS	Y	NR R
53874-0309-01	Belladonna Alk-Phenobarbital Oral Tablet 16.2 MG	$23.27						ALTURA PHARMACEUTICALS	Y	NR R
66213-0425-10	Donnatal Oral Tablet 16.2 MG	$471.68		$393.07	$0.00	$335.68		PBM PHARMACEUTICALS	O	NR R

Ingredients (Set ID: 1996)

Ingredient Name	Strength	Units	Active	Cmpnt ID
ATROPINE SULFATE	0.0194	MG	Y	C000055481
HYOSCYAMINE SULFATE	0.1037	MG	Y	C000620611
PHENOBARBITAL	16.0000	MG	Y	C000050066
SCOPOLAMINE HYDROBROMIDE	0.0065	MG	Y	C000114498

Exhibit B

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Manufacturers' Exchange

The Manufacturers' Data Exchange provides instructions for the submission of pharmaceutical product information to Wolters Kluwer Health including Medi-Span® and Facts & Comparisons®. Before pharmaceutical products can be added to our databases and publications, we must ensure we have accurate and up-to-date product information.

New Product Submission Instructions

Please download and complete the New Product Submission Form for each new product. Once completed, please submit the New Product Submission Form (DOC) and attachments to the Manufacturer's Exchange email address:

Email: mfgdata@wolterskluwer.com

Attachments to include:

- Package Insert
- Package Label
- FDA Approval Letter (NDA, ANDA, BLA)
- Product Image
- Relevant Clinical Study Data

Downloads:

- New Product Submission Form (DOC)
- Manufacturer Product Image Submission Guidelines (DOC)
- AWP Pricing Policy (PDF)

Additional Contact Information:

Fax: 317.735.5320

Phone: 855.539.7686

Address:
Wolters Kluwer Health - Medi-Span®
8425 Woodfield Crossing Blvd. Suite 490
Indianapolis, IN 46240

Request More Information

or call 855.539.7686

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Wolters Kluwer Health

Wolters Kluwer Health – MediSpan
Pricing Acquisition Department
8425 Woodfield Crossing Blvd. Suite 490
Indianapolis, IN 46240
P 800-388-8884, F 317-735-5320

New Product Submission Form

Please complete a separate form for each new product submission and e-mail completed form and supporting documents to: **mfgdata@wolterskluwer.com**

Please submit the following supporting documents for each new product:

- Package Insert
- Package Label
- FDA Approval Letter (NDA, ANDA, BLA)
- Product Image or Product Example (See page two for image guidelines)
- ***Please note: All products must have at least one identifier (NDC, UPC or HRI) and one price type (WAC, DP or SWP.)***

NDC Number	
InnerPack NDC* (if applicable)**	
HRI Number	
UPC Number	
Reference NDC (if applicable)	
Product Name	
Rx or OTC	
Package Size (ml, gm, each)	
Dosage Form	
Wholesale Acquisition Cost (WAC)	
Direct Price (DP)	
Manufacturer's Suggested Wholesale Price (SWP)	
Effective Date (Pricing)	
Active Ingredients & Strengths	
Descriptive Information **Imprint side 1/Imprint side 2** **Color/Shape** **Score marks/Coating** **Flavor/Clarity**	
Labeler/Manufacturer Name	
NDA/ANDA/BLA Number	
Contact Name, Email, and Telephone	

***If the product package has an inner NDC different from the outer NDC, please provide the NDC number for both the inner package and the outer package.**

Wolters Kluwer Health – MediSpan
Pricing Acquisition Department
8425 Woodfield Crossing Blvd. Suite 490
Indianapolis, IN 46240
P 800-388-8884, F 317-735-5320

Manufacturer Product Image Submission Guide

Wolters Kluwer Health, a major provider of computerized health-related content, collects and publishes Prescription and OTC drug images in our Drug Image Database. Pharmacists and healthcare providers rely upon visual verification of drug products to verify accuracy in medication dispensing and administration. Inclusion of your product images in our Drug Image Database is important to ensure patient safety.

We request your assistance to provide Wolters Kluwer Health with digital images of your drug products for inclusion in our Drug Image Database. Please send all image files as attachments to our manufacturer email address: mfgdata@wolterskluwer.com

Manufacturers may also send product examples (placebo), OTC products, and product images on CD to our corporate address:

Wolters Kluwer Health – MediSpan
Drug Image Dept.
8425 Woodfield Crossing Blvd. Suite 490
Indianapolis, IN 46240

In order to achieve image consistency, we have established submission guidelines displayed below:

- Image resolution 72 ppi or greater
- Image formats should be high-quality JPEG or PSD
- Image background should be a solid, neutral gray (see example below)
- Tablets/capsules should be photographed in pairs, positioned to show as much imprint information as possible.
- Image file names should include the product NDC e.g. 00002-5621-01.jpg
- Packaged products should generally be positioned so that the pertinent identifying text is right side up in the frame. If the product is much taller than it is wide, the product may be placed sideways to allow for a larger final image.
- Lighting should be positioned such that any texture or embossing on the subject is visible, with glare and shadows from the subject kept to a minimum.
- Packaging attributes should be included when applicable. Photos should include both box and inner tube for creams/ointments; box and inner bottle for ophthalmic and otic drops; outer box and wrapped patch for topical patches; stock bottle with liquid poured into medicine cup for oral liquids.

Image Examples